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A New Device That Protects from Minilaparotomy Wound Infection in Minimally-Invasive Approaches to Colon Cancer

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Background: Unfortunate complications in some patients who undergo minimally-invasive resections for colorectal cancer using a minilaparotomy are the development of postoperative wound infection or tumor recurrence at in the minilaparotomy site. These complications are potentially avoidable. In an effort to prevent these problems, we designed an easy-to-use device named the Lap-Protector™. The purpose of this study was to evaluate the efficacy of the Lap-Protector™ in preventing bacterial infection and tumor recurrence at minilaparotomy incision sites.

Patients and Methods: Ninety-eight colon cancer patients who underwent minimally-invasive resections using minilaparotomy (minilaparotomy or laparoscopic-assisted approach) with the assistance of the Lap-Protector™ between January 1999 and August 2000 were compared with 87 patients treated without this device between January 1997 and December 1998. Postoperative wound infection and tumor recurrence rates at the minilaparotomy site were retrospectively analyzed.

Results: Patient characteristics (age, sex, body mass index, and frequency of diabetes mellitus), tumor location, operative procedures, and pathological parameters were similar between the two groups. Four patients (4.6%) in the control group developed postoperative wound infections versus none in the Lap-Protector™ group (P=0.047). With a median follow-up of 8.3 (range, 1.3 to 19.3) and 29.7 (range, 8.4 to 54.4) months in the Lap-Protector™ group and control group, respectively, neither group has recorded a tumor recurrence at the minilaparotomy site.

Conclusion: The Lap-Protector™ appears to prevent wound infection after minimally-invasive resections for colon cancer using a minilaparotomy. Longer follow-up to evaluate tumor recurrence rates at the minilaparotomy site is necessary.

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Introduction

The conventional surgery for colon cancers has been challenged by the minimally-invasive approaches of laparoscopy[1-3] and minilaparotomy[4,5], which, in comparison, seem to allow faster recovery and decreased postoperative pain. At the completion of most laparoscopic colectomies, after laparoscopic mobilization of the bowel has been accomplished, a small 4 to 5-cm incision is made to allow extracorporeal anastomosis and removal of the specimen[3,6]. The minilaparotomy approach to colorectal resection, as reported by Fleshman et al[4]. and Fürstenberg et al[5]., involves utilizing the shortest possible incision through which all of components of the procedure can be performed. The use of a small incision, whether by minilaparotomy or by laparoscopy, resulted in an earlier return of bowel function and shorter hospital stay[4]. Thus, minilaparotomy is essential to performing either of these minimally-invasive approaches to colon tumor resections.

Unfortunate complications in some patients who undergo minimally-invasive resections for colorectal cancer using a minilaparotomy are the development of postoperative wound infection by intestinal bacteria[1,2,7] or tumor recurrence[2,8,9] at in the minilàparotomy site. These complications are potentially avoidable. In an effort to prevent these problems, we designed an easy-to-use device named the Lap-Protector™ in collaboration with Hakko Co., Ltd. (Catalog No. 9908T; Nagano, Japan). The purpose of this study was to evaluate the efficacy of the Lap-Protector™ in preventing infection and tumor recurrence (short term) at the minilaparotomy site after laparoscopic-assisted and minilaparotomy approaches to colon cancers.

Patients and Methods

Patient population

One-hundred eighty-five patients who underwent laparoscopic-assisted or minilaparotomy approaches for complete resection of colon cancer between January 1997 and August 2000 at Nagasaki University Hospital (Nagasaki, Japan) or Sasebo Municipal Hospital (Sasebo, Japan) were enrolled in this study. All patients included in this study underwent elective surgery in which the large bowel was opened. Exclusion criteria for both laparoscopic-assisted and minilaparotomy approaches included lack of informed patient consent, tumors larger than 6 ㎝, tumors infiltrating adjacent organs, intestinal obstruction or perforation, more than one carcinoma of the colon, and distant metastases. In addition, immunocompromised patients who had transplantation, those with long-term steroid administration, or those undergoing intensive chemotherapy were excluded from this study. American Joint Committee on Cancer classification and stage grouping were used to classify the tumors[10].

The Lap-Protector™ was first used in January 1999, and thereafter, until August 2000, on 98 patients (Lap-Protector™ group) undergoing minimally-invasive colonic resections for cancer. Prior to its use, from January 1997 to December 1998, we performed minimally-invasive procedures without this device on 87 patients (controls) with similar indications. The Lap-Protector™ group consisted of 11 patients who underwent laparoscopic-assisted approaches and 87 that underwent minilaparotomy approaches, whereas the control group consisted of 15 patients who underwent laparoscopic-assisted approaches and 72 patients with minilaparotomy approaches.

The two endpoints of postoperative infection and short-term tumor recurrence at the minilaparotomy wound were then evaluated and incidences retrospectively compared between study groups.

Lap-Protector™

The Lap-Protector™ consists of 2 flexible rings made of super-elastic alloys covered with polyurethane polyamide and a thin silicone rubber membrane that is attached to the outer edge of the two rings (Fig. 1-a). If the two rings are pulled apart, the device assumes a cylindrical shape with the outer diameter of each flexible ring 12 ㎝ (Fig. 1-b). This device can be used for minilaparotomy wounds with lengths ranging from 5 to 9 ㎝ and is available commercially at Hakko Co., Ltd. (Catalog No. 9908T; Nagano, Japan), at a cost of ¥7,000 ($58, at an exchange rate of U.S. $1=¥120).

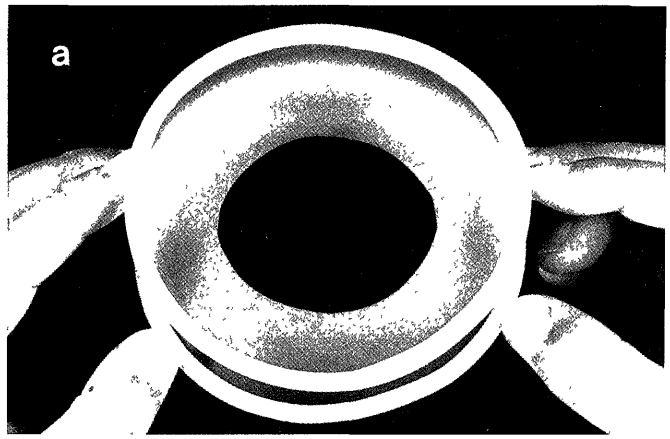

Fig. 1-a. Photograph of the Lap-Protector™ device.

Fig. 1-b. If the two rings are pulled apart, the device assumes a cylindrical shape.

Surgical techniques

In performing the laparoscopic-assisted approach, it was the surgeon's discretion whether or not to use a pneumoperitoneum. A small incision was made for extracorporeal bowel resection and anastomosis and removal of the specimens after laparoscopic mobilization of the bowel was accomplished. The Lap-Protector™ was used only at the minilaparotomy incision, not at the trocar sites.

Our definition of the minilaparotomy approach for resection of colon cancer implies that complete resection using conventional surgical techniques and instruments can be performed through a skin incision shorter than 7 ㎝. In performing the minilaparotomy approach, a small skin incision was made as the first operative step. The Lap-Protector™ was used at this minilaparotomy incision.

In preparation for inserting the Lap-Protector™, the operator must slide the bottom ring halfway through the opening of the top ring at an angle of approximately 45° such that half of the bottom ring is above

the plane of the top ring. The bottom ring was advanced slowly into the peritoneal cavity through the incision such that it abutted the peritoneal surface of the abdominal wall (Fig. 2). With the opposite end of the bottom ring snapped into the frontal abdominal wall also, the device formed a sandwich with the abdominal wall between the two rings, as the top ring remained on the skin surface of incision. The Lap-Protector™ provided a round and relatively wide opening in the abdomen due to the tension of the silicon rubber (Fig. 3).

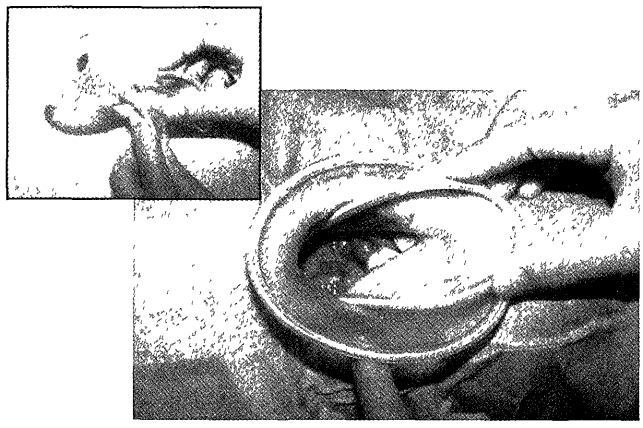

Fig. 2. Figure depicting insertion of the Lap-Protector™ device into the peritoneal cavity through the small incision.

Fig. 3. Figure depicting completion of attachment of the Lap-Protector™ device in the minilaparotomy wound.

At the conclusion of the operation, the surgeon changed gloves prior to performing peritoneal lavage with saline. The bottom ring was then removed by squeezing the ring and pulling it out of the peritoneal cavity slowly. Similar suture materials for closure of the minilaparotomy were used in both groups. The minilaparotomy wounds were not drained. Any intra-abdominal drainage tubes were brought out separately from the minilaparotomy wound.

Clinical management

Two to three liters of polyethylene glycol electrolyte solution given one day pre-operatively served as bowel preparation. No oral bowel preparation with antimicrobials was performed preoperatively, nor was systemic prophylactic administration conducted preoperatively or intraoperatively. All patients received a prophylactic, postoperative regimen of antibiotic (flomoxef sodium [Flumarin™, Shionogi Co. Ltd., Tokyo, Japan]), 2.0g/day intravenously for 5 consecutive days. No additional antibiotic was administered for patients who developed postoperative wound infection; rather, skin incision and wound drainage were performed only.

Wound infection

All data with respect to wound infection were collected during the period of postoperative recovery, prior to discharge from the hospital. A minilaparotomy wound was regarded as infected if there was a purulent discharge from the suture line or if there was a nonpurulent discharge that contained pathologic bacteria. Aerobic and anaerobic cultures were performed in the microbiology department of our Hospital. Since the Lap-Protector™ protects the minilaparotomy wound only, infectious complications from other sites in the operative fields (e.g. trocar sites or drainage tube sites) were excluded from this study.

Wound recurrence

Wound recurrence was defined as a tumor recurrence at the minilaparotomy wound in which the Lap-Protector™ was used. As the Lap-Protector™ serves to protect only the minilaparotomy wound, tumor recurrences at trocar sites, anastomotic recurrences, or disseminated peritoneal metastasis were excluded from this study.

Postoperative follow-up

No patients were lost to follow-up as of this writing (October, 2000). Median lengths of follow-up in the Lap-Protector™ group and Control group were 8.3 months (range, 1.3 to 19.3 months) and 29.7 months (range, 8.4 to 54.4 months), respectively. The Lap-Protector™ group included 22 patients whose follow-up periods were longer than one year following surgery.

Statistical analysis

Statistical analyses were performed using Statistica®

software (Statsoft, Tulsa, OK). Continuous data were expressed as mean and standard deviations, and statistical analyses were conducted using the unpaired t-test. Categorical data were analyzed by χ^2 test or Fisher's exact test. Each test was two-tailed and a P value of less than 0.05 was considered significant.

Results

Comparison of Lap-Protector™ and Control groups

Patient characteristics such as age, sex, body mass index[11] (defined as weight in kilograms divided by height in meters^2), frequency of diabetes mellitus, and tumor location (right colon vs. left colon) were similar between the two groups.

Mean values of minilaparotomy wound length in the Lap-Protector™ and Control groups were 6.7 ㎝ and 6.5 ㎝, respectively; a non-significant difference. Operative procedures including operative time, operative blood loss, type of operation, and method of anastomosis were similar between the two groups. No patients required blood transfusions.

Pathological parameters (maximal tumor diameter, number of lymph nodes removed, histologic type and tumor stage) were also similar between the two groups, as was length of postoperative hospital stay (Table 1).

Table 1. Comparison of patient characteristics between Lap-Protector™ and control groups.

Variables	Lap-Protector™ group (n=98)	Control group (n=87)	*P* value
Age (years)*	66.7 ± 12.0	65.3 ± 11.3	0.43
Sex**			0.77
Female/Male	41 (41.8)/57 (58.2)	39 (44.8)/48 (55.2)	
BMI (kg/m^2)*	22.5 ± 3.3	22.5 ±2.9	0.89
Diabetes mellitus**	3 (3.1)	4 (4.6)	0.71
Tumor location**			0.76
Right colon/Left colon	32 (32.7)/66 (67.4)	31 (35.6)/56 (64.4)	
Length of laparotomy wound (cm)*	6.7 ± 1.0	6.5 ± 1.3	0.25
Operation time (min.)*	170.8 ± 54.1	180.9 ± 55.9	0.21
Operative blood loss (ml)*	60.2 ± 118.2	77.3 ± 131.5	0.35
Operation**			0.17
Ileocecal resection	15 (15.3)	11 (12.6)	
Right hemicolectomy	11 (11.2)	6 (6.9)	
Transverse colectomy	5 (5.1)	8 (9.2)	
Left partial colectomy	7 (7.1)	5 (5.7)	
Sigmoid colectomy	56 (57.1)	45 (51.7)	
Surgical polypectomy	4 (4.1)	12 (13.8)	
Anastomosis**			0.85
Hand-sewn/ Stapled	80 (81.6)/18 (18.4)	70 (80.5)/17 (19.5)	
Maximal tumor diameter (cm)*	3.0 ± 17.6	2.7 ± 12.1	0.23
No. of lymph node removed*	10.6 ± 9.9	10.5 ± 9.2	0.94
Histologic type**¶			0.22
Well	64 (65.3)	51 (58.6)	
Moderately	30 (30.6)	35 (40.2)	
Poorly/ Mucinous	4 (4.0)	1 (1.2)	
Stage**			0.065
I	53 (54.1)	61 (70.1)	
II	28 (28.6)	14 (16.1)	
III	17 (17.4)	12 (13.8)	
Postoperative hospital stay (days)*	14.3 ± 6.5	15.5 ± 5.5	0.18

* Values are expressed as mean ± standard deviation, and statistical analyses are conducted by unpaired t-test.

** Values are expressed as number of patients (%), and statistical analyses are conducted by Fisher's exact test or χ^2 test.

¶ Well, Moderately, Poorly, and Mucinous denote well differentiated adenocarcinoma, moderately differentiated adenocarcinoma, poorly differentiated adenocarcinoma, and mucinous carcinoma.

Wound infection

None of the 98 patients in the Lap-Protector™ group developed wound infection postoperatively, whereas 4 of 87 patients (4.6%) in the Control group developed wound infection (P=0.047). Bacterial cultures minilaparotomy wounds suspected of infection revealed the following pathogens: Escherichia coli, Proteus spp., Pseudomonas aeruginosa, Bacteroides spp., and Enterococcus faecalis. All patients with suspected wound infections were treated by incision and drainage and received no additional antibiotic therapy.

There was no operative mortality in either group. Postoperative complications other than wound infection developed in 5 patients (5.7%; 3 intestinal obstructions, 1 intra-abdominal abscess, and 1 anastomotic bleeding) within Control group and 5 patients (5.1%; 4 intestinal obstructions and 1 subcutaneous hematoma) within Lap-Protector™ group. This difference was not statistically significant.

Wound recurrence during short-term follow-up

All patients in Lap-Protector™ group are alive without tumor recurrence, 22 of whom have follow-up exceeding 12 months. Six patients (6.9%) in the

Control group have developed tumor recurrence (metastasis to liver, lung, and/or ovary), 3 of whom are alive and 3 of whom have died of colon cancer.

No patients developed tumor recurrence at the minilaparotomy wound in either group. Similarly, no patient who underwent the laparoscopic-assisted approach developed tumor recurrence at port sites.

Discussion

The current study demonstrates that the Lap-Protector™ is useful in preventing infection of the minilaparotomy wound during minimally-invasive procedures (laparoscopic-assisted or minilaparotomy approaches) to colon cancers.

Assuming laparoscopy to be a less invasive approach, some investigators have anticipated reduced rates of wound complications such as infections and adhesions[6,12,13]. In fact, early reports suggested that laparoscopy in colorectal surgery might be associated with fewer postoperative infections, with rates of 3.6% and 1.2% for laparoscopic and 7.9% and 12.7% for open surgery reported in 2 series[12,13]. However, recent studies continue to report wound infection rates after laparoscopic-assisted approaches to colorectal cancer resections ranging from 2.9% to 8.2%[1,7]. Wound infection after the minilaparotomy approach also developed at a rate of 2.1% in a recent series[5]. Thus, wound infection persists as an important problem after minimally-invasive approaches.

Several wound-edge protectors, such as Steri-Drape™ (Minnesota Mining and Manufacturing Company, 3M, St. Paul, MN) or Vi-drape™ (Parke-Davis, Morris Plains, NJ) have been shown to prevent wound contamination and subsequent infection during conventional abdominal surgeries[14,15]. However, Nystrom et al. reported that a different wound ring drape, Op-drape™ (Triplus, Sweden), prevented neither contamination nor infection in a controlled, randomized study for elective colorectal surgery[16]. Thus, the efficacy of wound-edge drapes to prevent contamination and infection in colorectal surgery remains controversial[16]. Wound infections typically result from bacterial contamination with intestinal flora. Moreover, incidence of wound infections after extensive abdominal surgery appears related to factors other than simply operative contamination, such as reception of blood transfusions and patient immunocompetence[17]. While the studies mentioned above involved conventional open colorectal surgery, laparoscopic surgery has been shown to reduce the risk of infectious complications[18]. Further studies similar to these with minimally-invasive approaches, such as laparoscopy or minilaparotomy, will be necessary to demonstrate an effect in this population.

In some earlier studies, the incidence of wound tumor recurrence following laparoscopic colorectal cancer surgery far exceeded that reported for open surgery[2,8,9,19]. However, recent reports of large series have shown acceptably low numbers of wound tumor recurrences; 0% or less than 1%[20-23]. Several hypotheses as to the mechanism of wound seeding have been posed. Nduka et al[24]. have identified three factors that may predispose to an increased implantation rate: exfoliation of malignant cells following excessive manipulation by laparoscopic instruments, increased contact between the malignant cells and skin incisions, and the presence of a pneumoperitoneum. Preventing contamination of tumor cells during the laparoscopic-assisted procedure is an important issue in laparoscopic-assisted surgery. Approximately 80% of abdominal wall recurrences following laparoscopic colon cancer surgery occur within one year[8]. In the current study, none of 22 patients in the Lap-Protector™ group with follow-up beyond one year developed tumor recurrence at the minilaparotomy wound following minimally-invasive approaches. However, because the follow-up period of all patients in this study was limited, long-term follow-up for tumor recurrence in the minilaparotomy wound will be necessary.

Wound ring drapes (Steri-Drape™ etc) other than the Lap-Protector™ are not ideal for laparoscopic-assisted surgery, as these are designed as large drapes for use during laparotomy in conventional abdominal surgeries. In contrast, the Lap-Protector™ is designed specifically for laparoscopic-assisted surgeries as a small device that does not interfere with the surgeon's performance of the procedure. Furthermore, this new device (Lap-Protector™) is particularly useful in gasless laparoscopic surgery with minilaparotomy[25]. Since gasless laparoscopic-assisted surgeries do not require sealing of the abdominal wall for pneumoperitoneum, the Lap-Protector™ can be kept attached to the minilaparotomy site throughout the laparoscopic procedure.

The advantages of the Lap-Protector™ are four-fold: 1) simple utilization, 2) wound protection, as it does not cause damage to the minilaparotomy wound and reduces the chance that the minilaparotomy wound will come into contact with other tissues and organs, 3) wound access, as it provides a round and relatively wide opening in the abdomen due to the tension of the silicon rubber, and 4) low cost.

In summary, the Lap-Protector™ device represents a safe and useful method to maintain patency of the

small incisions within the abdominal wall performed during minimally-invasive surgical procedures, improve visibility, and prevent wound infections. Longer follow-up is necessary to evaluate its usefulness in preventing wound site tumor recurrences.

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